

PTO/SB/08A (08-00)

|   |   |    |   |                          |                          |
|---|---|----|---|--------------------------|--------------------------|
| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(use as many sheets as necessary)</i> |   |    |   | <i>Complete if Known</i> |                          |
|   |   |    |   | Application Number       | 10/729,421               |
|   |   |    |   | Filing Date              | December 5, 2003         |
|   |   |    |   | First Named Inventor     | SHYAMALA                 |
|   |   |    |   | Group Art Unit           | 1642                     |
|   |   |    |   | Examiner Name            | Not Assigned             |
|   |   |    |   | Attorney Docket Number   | 2300-20030 (PP20030.003) |
| Sheet   | 1 | of | 2 |                          |                          |

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document |                     |                                      | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document<br>MM-DD-YYYY | T <sup>6</sup> |
|--------------------|-----------------------|-------------------------|---------------------|--------------------------------------|---|---|----------------|
|                    |                       | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup><br>(if known) |   |   |                |
| AFS                | BA                    | PCT                     | WO 2004/092412      |                                      | Roche Diagnostics GMBH                          | 10-18-2004  |                |
| MCS                | BB                    | PCT                     | WO 2004/036190      |                                      | Gen-Probe Incorporated                          | 04-29-2004  |                |
|                    |                       |                         |                     |                                      |   |   |                |
|                    |                       |                         |                     |                                      |   |   |                |
|                    |                       |                         |                     |                                      |   |   |                |

|                       |                    |                    |          |
|-----------------------|--------------------|--------------------|----------|
| Examiner<br>Signature | <i>M. M. Kelly</i> | Date<br>Considered | 12/16/05 |
|-----------------------|--------------------|--------------------|----------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

<sup>2</sup> See attached Kinds of U.S. Patent Documents.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>3</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

|  |              |                          |                  |                        |                          |
|--|--------------|--------------------------|------------------|------------------------|--------------------------|
| Substitute for form 1449B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |              | <b>Complete if Known</b> |                  |                        |                          |
|  |              | Application Number       | 10/729,421       |                        |                          |
|  |              | Filing Date              | December 5, 2003 |                        |                          |
|  |              | First Named Inventor     | SHYAMALA         |                        |                          |
|  |              | Group Art Unit           | 1642             |                        |                          |
| Examiner Name  | Not Assigned |                          |                  |                        |                          |
| Sheet  | 2            | of                       | 2                | Attorney Docket Number | 2300-20030 (PP20030.003) |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---|-----------------------|---|----------------|
| Examiner Initials*                                | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>1</sup> |
| MFS   | CA                    | SHYAMALA et al., "PERFORMANCE CHARACTERISTICS OF THE VALIDATED AND IMPROVED QUALITATIVE AND QUANTITATIVE TARGET-CAPTURE PCR WNV NAT ASSAYS," Scientific Section, Transfusion, Vol. 44, Supplement (2004) SP377  |                |
|   | CB                    | BUSCH et al., "WEST NILE VIRUS RNA DYNAMICS AND ANTIBODY EVOLUTION BASED ON FOLLOW-UP OF VIREMIC BLOOD DONORS," Scientific Section, Transfusion, Vol. 44, Supplement (2004) P6-030A   |                |
| MFS   | CC                    | CLINE et al., "GEN-PROBE ALTERNATIVE WNV ASSAY: A TMA-BASED CONFIRMATORY ASSAY FOR WEST NILE VIRUS," Scientific Section, Transfusion, Vol. 44, Supplement (2004) SP368  |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |

|                    |                  |                 |          |
|--------------------|------------------|-----------------|----------|
| Examiner Signature | <i>M. K. Lee</i> | Date Considered | 12/16/05 |
|--------------------|------------------|-----------------|----------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

<sup>1</sup> Applicant is to place a check mark here if English language Translation attached.



<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

|  |   |                          |                  |                        |                          |
|--|---|--------------------------|------------------|------------------------|--------------------------|
| Substitute for form 1449B/PTO<br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(use as many sheets as necessary) |   | <b>Complete if Known</b> |                  |                        |                          |
|  |   | Application Number       | 10/729,421       |                        |                          |
|  |   | Filing Date              | December 5, 2003 |                        |                          |
|  |   | First Named Inventor     | SHYAMALA         |                        |                          |
|  |   | Group Art Unit           |                  |                        |                          |
| Examiner Name  |   |                          |                  |                        |                          |
| Sheet  | 2 | of                       | 2                | Attorney Docket Number | 2300-20030 (PP20030.003) |

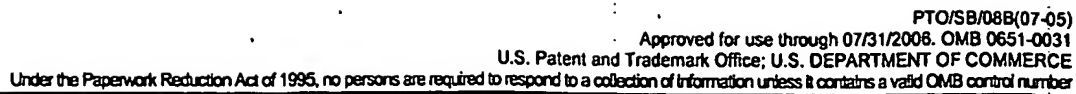
| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---|-----------------------|---|----------------|
| Examiner Initials*                                | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>1</sup> |
| MPS   | AC1                   | ANDERSON et al., "ISOLATION OF WEST NILE VIRUS FROM MOSQUITOES, CROWS, AND A COOPER'S 'HAWK IN CONNECTICUT", <i>Science</i> (1999) <u>286</u> : 2331-2333   |                |
|   | AC2                   | BERTHET et al., "EXTENSIVE NUCLEOTIDE CHANGES AND DELETIONS WITHIN THE ENVELOPE GLYCOPROTEIN GENE OF EURO-AFRICAN WEST NILE VIRUSES", <i>J. of General Virol.</i> (1997) <u>78</u> : 2293-2297.   |                |
|   | AC3                   | BRIESE et al., "DETECTION OF WEST NILE VIRUS SEQUENCES IN CEREBROSPINAL FLUID", <i>The Lancet</i> (2000) <u>355</u> : 1614-1615.  |                |
|   | AC4                   | BRINTON, "THE MOLECULAR BIOLOGY OF WEST NILE VIRUS: A NEW INVADER OF THE WESTERN HEMISPHERE", <i>Ann. Rev. Microbiol.</i> (2002), <u>56</u> : 371-402.  |                |
|   | AC5                   | BURT et al., "PHYLOGENETIC RELATIONSHIPS OF SOUTHERN AFRICAN WEST NILE VIRUS ISOLATES", <i>Emerging Infectious Diseases</i> (2002) <u>8</u> (8): 820-826.   |                |
|   | AC6                   | LANCIOTTI et al., "ORIGIN OF THE WEST NILE VIRUS RESPONSIBLE FOR AN OUTBREAK OF ENCEPHALITIS IN THE NORTHEASTERN UNITED STATES", <i>Science</i> (1999), <u>286</u> : 2333-2337.   |                |
|   | AC7                   | LANCIOTTI et al., "RAPID DETECTION OF WEST NILE VIRUS FROM HUMAN CLINICAL SPECIMENS, FIELD-COLLECTED MOSQUITOES, AND AVIAN SAMPLES BY A TAQMAN REVERSE TRANSCRIPTASE-PCR ASSAY", <i>J. Clin. Microbiol.</i> (2000) <u>38</u> : 4066-4071.                       |                |
| MPS   | AC8                   | LANCIOTTI et al., "NUCLEIC ACID SEQUENCE-BASED AMPLIFICATION ASSAYS FOR RAPID DETECTION OF WEST NILE AND ST. LOUIS ENCEPHALITIS VIRUSES", <i>J. Clin. Microbiol.</i> (2001) <u>39</u> : 4506-4513.  |                |
|   |                       |   |                |
|   |                       |   |                |
|   |                       |   |                |

|                    |                       |                 |          |
|--------------------|-----------------------|-----------------|----------|
| Examiner Signature | <i>M. [Signature]</i> | Date Considered | 12/16/05 |
|--------------------|-----------------------|-----------------|----------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

<sup>1</sup> Applicant is to place a check mark here if English language Translation attached.



**(Use as many sheets as necessary)**

|       |   |    |   |
|-------|---|----|---|
| Sheet | 1 | of | 1 |
|-------|---|----|---|

|                               |                         |
|-------------------------------|-------------------------|
| <b>Application Number</b>     | 10/729,421              |
| <b>Filing Date</b>            | 12-05-2003              |
| <b>First Named Inventor</b>   | Venkatakrishna Shyamala |
| <b>Art Unit</b>               | 1642                    |
| <b>Examiner Name</b>          | M. Franco Salvoza       |
| <b>Attorney Docket Number</b> | PP020030.0003           |

[illegible]

M. J. J. J.

01/18/04

Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

***If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.***